

KIRKLAND & ELLIS LLP MEMO ENDORSED
AND AFFILIATED PARTNERSHIPS

Robert W. Allen, P.C.
To Call Writer Directly:
+1 212 390 4060
bob.allen@kirkland.com

601 Lexington Avenue
New York, NY 10022
United States

+1 212 446 4800

www.kirkland.com

Facsimile:
+1 212 446 4900

February 9, 2021

VIA CM/ECF

The Hon. Kenneth M. Karas
United States District Court for the
Southern District of New York
The Hon. Charles L. Brieant Jr.
Federal Building and United States Courthouse
300 Quarropas St., Courtroom 521
White Plains, NY 10601-4150

**Re: *Regeneron Pharms., Inc. v. U.S. Dep't of Health & Human Servs., et al.*,
No. 7:20-cv-10488-KMK**

Dear Judge Karas:

Pursuant to this Court's February 2, 2021, order, Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron") respectfully responds to Defendants' February 2 letter requesting leave to move this Court for a stay of this case.

Regeneron filed this suit to obtain a ruling that the Most Favored Nation Rule issued by Defendants on November 20, 2020 ("MFN Rule"), violates the law and must be vacated. In its opinion and order granting a preliminary injunction, this Court held that Regeneron is "more likely than not to prevail" in its challenge because the MFN Rule was promulgated without adherence to proper notice-and-comment requirements. Defendants could have immediately appealed that ruling, but they chose not to, leaving the court's decision and reasoning undisturbed.

Having entered a preliminary injunction on terms that were sufficiently compelling that the government declined to appeal, the next logical step is for this Court to enter summary judgment on the same terms, not to grant the government a stay while the government attempts to squeeze some advantage out of its improper rule. There is no serious question that the MFN Rule is illegal. And there is no serious question that the proper remedy for the procedurally flawed MFN Rule is immediate vacatur of the rule. "[V]acatur is the normal remedy' for a procedural violation." *NRDC v. Wheeler*, 955 F.3d 68, 85 (D.C. Cir. 2020) (quoting *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1109 (D.C. Cir. 2014)). That is particularly so when the procedural violation was a "[f]ailure to provide the required notice and to invite public comment"—a "fundamental flaw"—and there are no "serious disruptive consequences of vacatur." *Id.* (quoting *Heartland Reg'l Med. Ctr. v. Sebelius*, 566 F.3d 193, 199 (D.C. Cir. 2009)); *see also Allina*, 746 F.3d at 1111

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(vacating rule given “deficient notice”). Importantly, and contrary to the government’s suggestion in its letter regarding summary judgment, there is no exception to these well-established principles for interim final rules (IFRs) when, as here, the government seeks to use an invalid IFR as a substitute for a valid notice of proposed rulemaking (NPRM). *See, e.g., Mack Trucks, Inc. v. EPA*, 682 F.3d 87, 95 (D.C. Cir. 2012) (holding that IFR issued without notice and comment “must be vacated,” even though agency was “currently in the process of promulgating a final rule—with the benefit of notice and comment—on this precise issue,” and even if “vacatur of the IFR ... will be of limited practical impact”); *California v. Azar*, 911 F.3d 558, 580-81 (9th Cir. 2018).

To the contrary, the fact that the government seeks to leverage its improper IFR to short-circuit a proper NPRM is all the more reason for proceeding to judgment. Contrary to the government’s apparent view, comments on an invalid IFR are no substitute for a valid comment period for a properly noticed NPRM, as comments on an invalid IFR tend to focus on its procedural flaws and purported immediate effect, which are issues that would not even arise with a valid NPRM. *Little Sisters of the Poor* is not to the contrary and is inapposite both procedurally and substantively. First, in that case, the government appealed the preliminary injunction against its IFR, so the case provides no support for the government’s suggestion that it can forestall summary judgment when an IFR is preliminarily enjoined and the government *declines* to appeal, as here. Second, by the time that case reached the Supreme Court, the only challenge was to a *final* rule. By holding that a defect in an IFR is not necessarily a valid basis for invalidating a *final* rule due to harmless-error principles, the Court in no way suggested there was no error at all or that an error in the IFR should go unredressed when the IFR itself is at issue.

The government’s arguments for a stay lack merit. First, it contends that a stay will allow it to “proceed[] with the very notice-and-comment rulemaking process sought by Plaintiff.” Letter.2. But bypassing notice-and-comment on a valid NPRM based on recycled comments on an invalid IFR is decidedly not the notice-and-comment rulemaking process Regeneron seeks. Many of the comments on the IFR, including a substantial portion of Regeneron’s comments, addressed procedural defects with the IFR. Those comments would not be germane in the context of an NPRM, where the comments would not be rushed and could focus exclusively on substance. Thus, to be clear, what Regeneron seeks is a valid notice-and-comment period for a valid NPRM. That the government intends to deny Regeneron the notice-and-comment process it seeks is thus a powerful reason to deny the stay.¹

¹ The comment period for IFR was deficient in other respects as well. For example, Defendants did not open the entire MFN Rule to comment; instead, they sought comments only on peripheral issues. *See, e.g.,* 85 Fed. Reg. 76180, 76246 (Nov. 27, 2020) (inviting “comments on adjustments to the MFN Model that could be considered for future rulemaking *while preserving the innovative approach to payment in the MFN Model*” (emphasis added)); *id.* at 76191 (seeking comment “on whether all blood related, plasma derived, and human tissue products should be included in or excluded from the MFN Model”). Defendants’ invitation of selective comments does not “provid[e] a forum for the robust debate of competing and frequently complicated policy considerations having far-reaching implications,” and thus does not “foster reasoned decisionmaking.” *NRDC v. NHTSA*, 894 F.3d 95, 115 (2d Cir. 2018).

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Second, the government vaguely speculates that the ongoing post-rule process “may significantly affect or substantially narrow the issues to be considered by this Court or obviate the need for the Court to consider any issues at all.” *Id.* But none of that matters given the procedural flaws of the MFN Rule, which, as noted, are dispositive as to the MFN Rule. The government contends that “[p]roceeding with litigation” would be “inefficient” and “needless,” *id.* at 3, but that assertion blinks reality. The government appears to concede the invalidity of the MFN Rule, and the well-established remedy for a procedurally invalid rule (including an interim rule) is vacatur. There is essentially nothing left in dispute to litigate in this case.

Third, the government argues that a stay “would not prejudice” Regeneron. *Id.* at 2. That is simply wrong. As the attached declaration details, Regeneron is very much prejudiced by the continued existence of the MFN Rule, even while the rule’s implementation has been preliminarily enjoined. Physicians and organizations have expressed confusion regarding whether and how the MFN Rule might eventually be implemented, and Regeneron’s competitors have exploited that confusion. The uncertainty produced by the still-extant MFN Rule regarding potential changes to reimbursement methodology affects physician prescribing decisions—limiting EYLEA access for new and existing patients—while creating a competitive advantage for other products, all leading to a decrease in EYLEA sales now and in the future. These harms are magnified, moreover, the longer the MFN Rule remains in a state of limbo—undefended by the government, and to be replaced (maybe) by Defendants (someday) with a new rule (contents unknown).

All of this is precisely why Regeneron filed suit not just to temporarily suspend implementation of the MFN Rule, but to obtain a ruling that the MFN Rule is invalid and must be vacated. Having begun that process, Regeneron is entitled to finish it.


Sincerely,

/s/ Robert W. Allen, P.C.
Robert W. Allen, P.C.

Copies to: All Counsel of Record (via CM/ECF)
Defendants' application is granted. (See Dkt. No. 55.) The case is stayed for 90 days. Consideration of the appropriate factors favors this outcome. See *Catskill Mountains Chapter of Trout Unlimited, Inc. v. EPA*, 630 F. Supp. 2d 295, 304 (S.D.N.Y. 2009). The Parties are instructed to file a status letter by May 10, 2020.

Plaintiff's request for a pre-motion conference for leave to file a motion for summary judgment is denied without prejudice. (See Dkt. No. 54.) Plaintiff may renew its request when the stay ends.

2/10/21

SO ORDERED

KENNETH M. KARAS U.S.D.J.